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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,262	08/05/2003	Alan M. Myers	ISU-003BX	7055

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EXAMINER	
FOX, DAVID T	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 06/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/634,262	MYERS ET AL.	
	Examiner	Art Unit	
	David T. Fox	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The application should be reviewed for errors. Errors appear, for example, on page 13 of the specification, line 12, where "know" should be replaced with ---known--; on page 16, line 15, where "indicates" should be replaced with ---indicated---; on page 22 of the specification, line 6, where "*Tobaccum nicotiana*" should be replaced with --*Nicotiana tabacum*--; and on page 48, line 2, where "designates" should be replaced with ---designated---.

The paper copy and computer readable format of the Sequence Listing need to be corrected, since they list an incorrect serial number for the first parent application. On page 1 of the Sequence Listing, item <150>, "08/062,102" should be replaced with ---08/968,542---. Furthermore, parent application serial number 09/554,467 should also be listed on the paper copy of the Sequence Listing, as well as the instant application serial number. See page 1 of the computer readable format of the Sequence Listing.

The specification is objected to on page 1 for its omission of the PCT application, and for its incorrect designation of the relationship to the first parent application. The first paragraph of the specification should be replaced with the following:

---This application is a continuation application of application Serial No. 09/554,467 filed 12 May 2000, now U.S. Patent 6,639,125, which is a 371 of PCT/US98/24225 filed 12 November 1998, which is a continuation-in-part of application Serial No. 08/968,467 filed 12 November 1997, now U.S. Patent 5,981,728, all of which are incorporated by reference herein.---

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to isolated nucleic acid molecules encoding a starch synthase, comprising an N-terminal arm from any source and of any sequence, a C-terminal catalytic region from any source and of any sequence, and a central sequence which has as low as 75% homology with nucleotides 2425 to 5022 of SEQ ID NO:1; vectors and plants transformed therewith; and methods for their use to produce starch from transformed cells. In contrast, the specification only describes a maize gene encoding a starch synthase II from maize, wherein the gene has the sequence of SEQ ID NO:1 and encodes SEQ ID NO:12. No description is provided for any hybrid starch synthase gene from multiple sources and of multiple sequences, or for any sequence variants of the particularly claimed internal region of the gene. In fact, the particular 2425 to 5022 nucleotide region of SEQ ID NO:1, or its encoded peptide, is nowhere recited in the specification. Thus, the specification fails to describe a sequence with even 100% homology to nucleotides 2425 to 5022 of SEQ ID NO:1, let alone the genus of sequences with as low as 75% homology thereto.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a

precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." Id.

See MPEP Section 2163, page 156 of Chapter 2100 of the August 2001 version, column 2, bottom paragraph, where it is taught that

> [T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description

Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

See also Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

See also University of California v. Eli Lilly and Co., 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn to isolated nucleic acid molecules encoding a starch synthase, comprising an N-terminal arm from any source and of any sequence, a C-terminal catalytic region from any source and of any sequence, and a central sequence which has as low as 75% homology with nucleotides 2425 to 5022 of SEQ ID NO:1; vectors and plants transformed therewith; and methods for their use to produce starch from transformed cells or transformed plants of any species.

In contrast, the specification only describes a maize gene encoding a starch synthase II from maize, wherein the gene has the sequence of SEQ ID NO:1 and

encodes SEQ ID NO:12. No description is provided for any hybrid starch synthase gene from multiple sources and of multiple sequences, or for any sequence variants of the particularly claimed internal region of the gene. In fact, the particular 2425 to 5022 nucleotide region of SEQ ID NO:1, or the peptide encoded thereby, is nowhere recited or characterized in the specification. Furthermore, no guidance is provided for transforming a multitude of divergent plant species with the multitude of non-exemplified sequences or hybrid genes, or the obtention of starch therefrom. In other words, no guidance is provided for how to use the claimed sequence variants and hybrid genes.

Constructing hybrid starch synthase genes for use in different plant host species is unpredictable. See Salehuzzaman et al, who teach that a hybrid starch synthase gene encoding a potato N-terminal portion and a cassava C-terminal portion was only effective in complementing starch synthase mutants in potato when additional mutations were introduced, due in part to the different properties of the different enzymes from different sources, wherein the use of an unaltered potato transit peptide did not completely complement the mutants even in potato hosts (see, e.g., page 1311, Abstract; page 1313).

Furthermore, the sequence alterations in the central portion of the starch synthase gene are unpredictable regarding the maintenance of their ability to encode a starch synthase. See Chang et al, who teach a gene with 65.6% overall similarity and 79.2% local similarity to nucleotides 2425 to 5022 of SEQ ID NO:1, which gene is characterized as a pathogen resistance gene rather than a starch synthase gene.

The process of modifying starch accumulation in transgenic plants, via transformation with genes encoding proteins involved in starch synthesis, is particularly unpredictable. See Kossmann et al (1995; Progress in Biotechnology, Volume 10), who teach the lack of influence of antisense potato starch accumulation genes on branching or phosphate content of starch (page 275, third through fifth full paragraphs), the difficulty inherent in isolating individual starch synthesis enzymes, including starch synthase, or their corresponding genes (paragraph bridging pages 275 and 276), and the lack of correlation between reduction of branching enzyme gene activity and branching of starch in transgenic plants (see, e.g., page 277, penultimate paragraph). See also Nakatani et al, page 468, Abstract, who teach the lack of involvement of starch synthase in starch accumulation in sweet potato.

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to identify and isolate a multitude of non-exemplified sequence fragments or variants from a multitude of non-exemplified sources encoding a multitude of domains of starch synthase, to construct hybrid genes comprising the multitude of sequence variants and sequences from various sources, and to evaluate these sequence variants or hybrid genes for their ability to actually encode a starch synthase. Undue experimentation would have also been required to evaluate the ability of these sequence variants and hybrid genes to function in host cells transformed therewith to materially affect starch synthesis.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 5-9 of U.S. Patent No. 6,639,125. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art to utilize the maize starch synthase genes with particular domains, including nucleotide 2425 of SEQ ID NO:1 as one boundary, for plant transformation therewith and starch production therefrom, as claimed in the patent; to obtain the maize starch synthase genes with particular domains, including nucleotide 2425 of SEQ ID NO:1 as one boundary, for plant transformation therewith and starch production therefrom, as claimed in the instant application.

Claims 1-7 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest an isolated nucleic acid molecule comprising a sequence with at least 75% homology to nucleotides 2425 to 5022 of SEQ ID NO:1 or starch synthase genes comprising it, or hosts transformed therewith.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (571) 272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (571) 272-0804. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

June 22, 2004

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638